K020090

SECTION VI: 510(k) SUMMARY
[as required by section 807.92(c)]

FEB 11 2002

A. Submitter's Information:

Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.296.3000
Facsimile:	610.296.4591
Contact Person:	Tim Stoudt
Title:	Quality Assurance Engineering Manager
Date Submission Prepared:	November 13, 2001

B. Device Information:

Trade name:	Not assigned at the time of submission
Classification Name(s):	Catheter Introducer (21 CFR §870.1340), Vessel Dilator (21 CFR §870.1310), Percutaneous Catheter (21 CFR §870.1250)
Common or usual name(s):	Transseptal Introducer Set

C. Legally marketed device to which equivalence is claimed:

Thomas Medical Products, Inc., Transseptal Introducer Set (K932619)

D. Description of the device:

The Thomas Medical Products Inc. modified Transseptal Introducer Sets are designed to provide a conduit to deliver diagnostic and therapeutic catheters into the left side of the heart through the interatrial septum. Each modified Transseptal Introducer Set consists of; a sheath, a dilator, and a "J" tip guidewire.

In addition, a standard 12 cc syringe, a 18 gage XTW introducer needle, and a pre-dilator may also be packaged with the Transseptal Introducer Sets as optional accessories.

E. Intended use of the device:

The Transseptal Introducer Set is indicated for the introduction of various types of cardiovascular catheters into the left side of the heart through the interatrial septum.

F. Summary of the technological characteristics of the device compared to the predicate device:

The technological characteristics of the device are the same as those of the predicate device.

G. Substantial equivalence rationale:

The Thomas Medical Products Inc. modified Transseptal Introducer Sets have the same general intended use / indications for use and technological characteristics as other previously cleared devices. Therefore, based on these similarities, the Thomas Medical Products, Inc. modified Transseptal Introducer Sets are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Mr. Tim Stoudt
Manager, Quality Engineering
Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355

Re: K020090
Transseptal Introducer Kit
Regulation Number: 870.1340
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: January 25, 2002
Received: January 28, 2002

Dear Mr. Stoudt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good

Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020090

Device Name: Transseptal Introducer Kit

Indications For Use:

For the introduction of various types of cardiovascular catheters into the left side of the heart through the interatrial septum.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020090

(Optional Format 1-2-96)